

## REMARKS

Reconsideration of the claims currently pending and withdrawal of the outstanding rejections in the instant application as set forth in the Office action mailed June 15, 2007 are respectfully requested in view of the arguments presented herein.

### **I. Status of the Claims**

Claims 1-6 and 9-30 are pending in the application.

Claims 7 and 8 are canceled.

### **II. Claim Rejection Under 35 U.S.C. §112, First Paragraph**

The Examiner has rejected claims 27-28 under 35 U.S.C. 112, first paragraph. The Examiner has asserted that claims 27 and 28 contain subject matter that was not described in the specification in such a way as to enable one skilled in the art to make and/or use the invention. Specifically, the Examiner has asserted that the recitation "immobilized alkali" is considered non-enabling, since there is no indication that Amberjet 4400 comprises an alkali metal. This rejection is respectfully traversed for the following reasons.

The standard for enablement is that one skilled in the art must be able to make and use the invention without undue experimentation. Further, a patent need not teach, and preferably omits, what is well known in the art. See MPEP, Section 2164.01, and the cases cited therein.

As pointed out by the Examiner, the specification teaches at page 7, lines 5 to 8, the use of an immobilized alkali, and provides an illustrative example thereof, e.g., Amberjet 4400 (OH). First, one skilled in the art of chemistry, and in particular polymer chemistry, would clearly know the meaning of "immobilized alkali", based both on the specification and knowledge commonly available in the art. Moreover, the specification provides an example of such an immobilized alkali, i.e., the strongly basic anion exchange resin, Amberjet 4400, having ammonium ions (NH<sub>4</sub><sup>+</sup>) as its matrix active group. The product description of Amberjet 4400 is provided in Appendix A, which describes it as a strongly basic anion exchanger. This description supports and

correlates with the language used in the specification, "immobilized alkali". Thus, one skilled in the art would clearly be able to make and use an immobilized alkali based upon such knowledge and information.

The Examiner's remarks regarding an "alkali metal" are completely irrelevant to the present analysis. Indeed, an alkali *metal* has absolutely nothing to do with an immobilized alkali in the present instance – which refers merely to a substance having basic properties (i.e., alkali) that is immobilized, e.g., on a resin. See Appendix B which provides definitions for the term, "alkali" from three different sources, all of which support the arguments provided above.

In view of the above remarks, it is submitted that claims 27 and 28 comply with the enablement requirement of 35 U.S.C. 112, first paragraph; withdrawal of this rejection of the claims is therefore respectfully requested.

### **III. Claim Rejection Under 35 U.S.C. §112, Second Paragraph**

The Examiner has rejected claim 24 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This rejection is respectfully traversed for the following reasons.

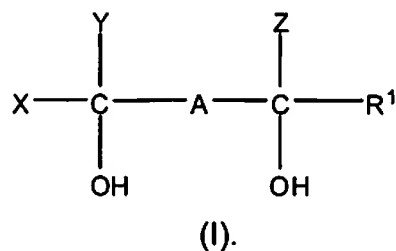
The second paragraph of 35 U.S.C. §112 requires that "the specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as the invention". The question to be addressed then, is whether the metes and bounds of the subject matter claimed are clear to one of skill in the art. The answer to the claim in question here is undoubtedly "yes" for the following reasons.

Claim 24 depends upon claim 9, which depends from claim 1. Claim 24 recites the following:

"The process of claim 9, wherein said contacting results in formation of P-C(O)-Q, and said passing step is effective to remove said P-C(O)-Q from said composition".

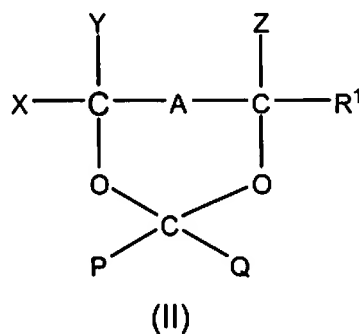
Claim 24, when reviewed in the context of claim 1, clearly points out the subject matter to be protected.

Claim 1 recites a process for the preparation of a polymerizable composition comprising a polymerizable monomer of formula I:

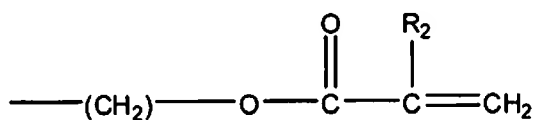


The process comprises the steps of:

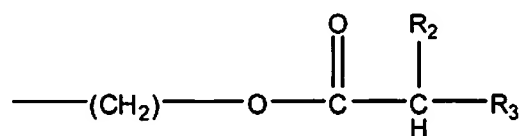
(i) contacting a compound of formula II



with an immobilized acid to thereby form a composition comprising the monomer of formula (I) and an acid by-product thereof, wherein X, Y, Z, P, and Q are independently selected from a hydrocarbyl group or hydrogen, A is  $(\text{CH}_2)_n$ , wherein n is 0 or 1;  $\text{R}^1$  corresponds to either formula IIIA or formula IIIB



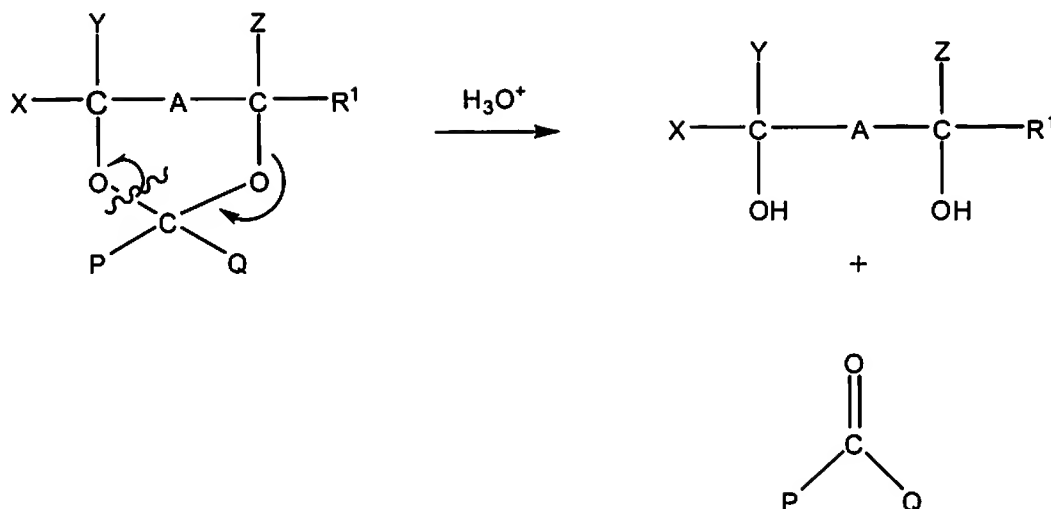
IIIA



IIIB

where  $\text{R}_2$  is selected from the group consisting of H, methyl, ethyl, propyl, and butyl, and  $\text{R}_3$  is an unsaturated  $\text{C}_{2-5}$  alkyl; and (ii) neutralizing the composition of step (i) to thereby provide a composition comprising the monomer of formula I and a cross-linker.

Thus, values for each of the subject variables is provided in the claims – clearly delineating the metes and bounds of the invention. The reaction encompassed in the subject claims is provided below:



By virtue of formation of the monomer of formula I, one skilled in the chemical arts would clearly understand formation of the compound, P-C(O)-Q, recited in claim 24. Moreover, a specific example of the subject reaction is provided in the instant application as Figure 1. Further, based upon the structure explicitly recited, along with recited values of P and Q, it is submitted that claim 24 as currently recited is precise, clear, and unambiguous. Thus, it is submitted that claim 24 in its present form meets the requirements of U.S.C. §112, second paragraph. Withdrawal of this ground of rejection is thus respectfully submitted.

#### IV. Rejection Under 35 U.S.C. §103

As stated in the current Office action under item (4), the Examiner has withdrawn the previous rejection of the claims under 35 U.S.C. §103(a) as being unpatentable over Mancini et al. (U.S. Patent No. 4,056,496) in view of Mitra et al. (U.S. Patent No. 5,212,015). By virtue of the withdrawal of such rejection, the Examiner has acknowledged that the subject claims are non-obvious over the combination of Mancini et al. and Mitra et al.

Thus, the question addressed in the arguments which follow is whether the deficiencies of Mancini and Mitra are made up by the additional references now relied upon by the Examiner. Applicant respectfully submits that the answer to this question is "no" for the reasons which follow.

**A. GROUNDS OF REJECTION**

Claims 1-6, and 9-26, 29 and 30 stand rejected under 35 U.S.C. §103(a) as unpatentable over Mancini et al., U.S. Patent No. 4,056,496 in view of Mitra et al., U.S. Patent No. 5,212,015, as evident in view of Goto et al. (U.S. Patent No. 3,845,164), and Williamson et al. (U.S. Patent No. 6,239,298).

This rejection is respectfully traversed in view of the remarks that follow.

**B. THE CLAIMED INVENTION**

The claimed invention is directed to a process for preparing a polymerizable composition, where the resulting polymerizable composition comprises a polymerizable monomer and advantageously, small amounts of a cross-linker.

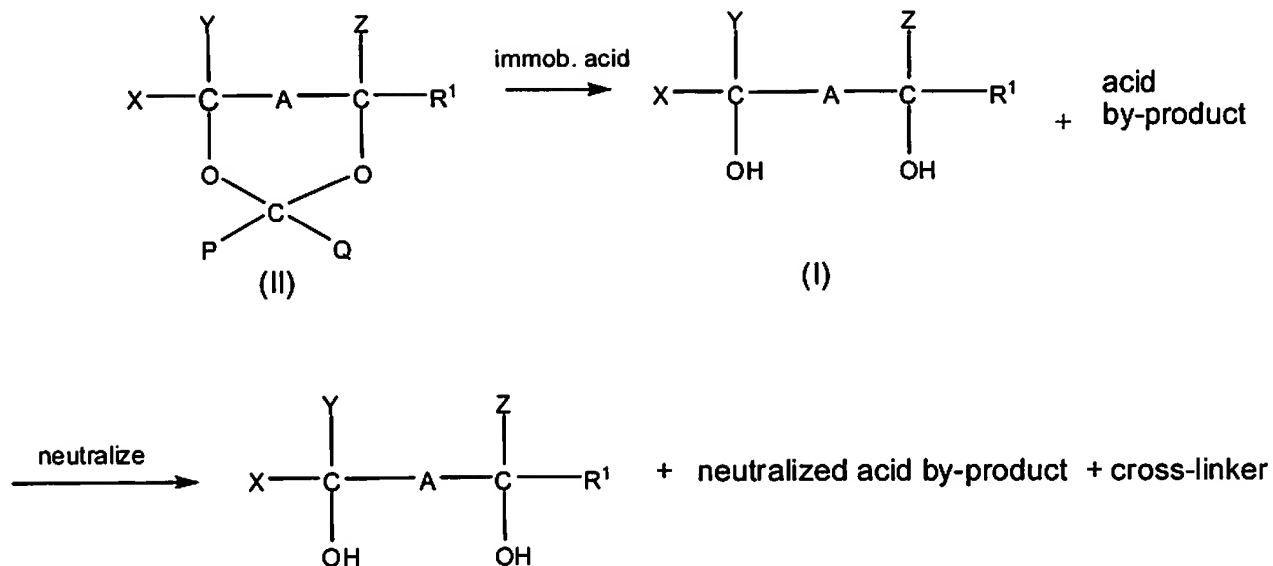
A characterization of the claims was provided in Applicant's previous reply, however, the salient features are reiterated here for ease of reference.

The Applicant's claimed process, as embodied in independent claim 1, includes the following steps:

(i) contacting a compound of formula (II) with an immobilized acid to form a composition comprising the monomer of formula (I) and an acid by-product thereof, and

(II) neutralizing the composition of step (i) to thereby provide a composition comprising the monomer of step (i) and a cross-linker.

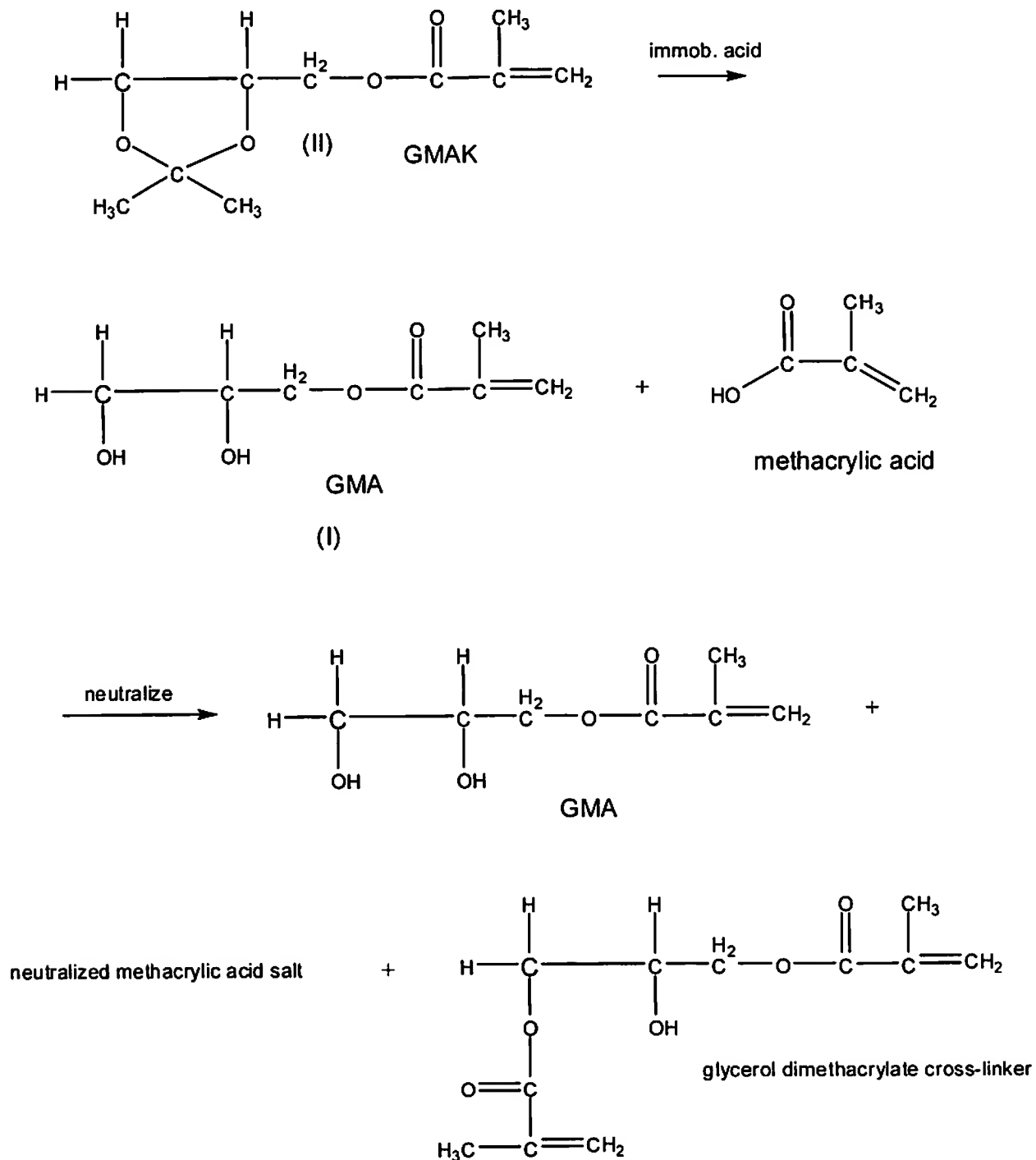
The claimed process is shown generally in the reaction scheme below.



Variable	Selected From
X	Hydrocarbyl*, H
Y	Hydrocarbyl*, H
Z	Hydrocarbyl*, H
P	Hydrocarbyl*, H
Q	Hydrocarbyl*, H
A	CH <sub>2</sub> or absent
R <sup>1</sup>	$\text{---}(\text{CH}_2)\text{---O---}\overset{\text{O}}{\parallel}\text{C---}\overset{\text{R}_2}{\underset{ }{\text{C}}}=\text{CH}_2$ <p>or</p> $\text{---}(\text{CH}_2)\text{---O---}\overset{\text{O}}{\parallel}\text{C---}\overset{\text{R}_2}{\underset{\text{H}}{ }{\text{C}}}\text{---R}_3$
R <sub>2</sub>	H, -CH <sub>3</sub> , -CH <sub>2</sub> CH <sub>3</sub> , -CH <sub>2</sub> CH <sub>2</sub> CH <sub>3</sub> , -CH <sub>2</sub> CH <sub>2</sub> CH <sub>2</sub> CH <sub>3</sub>
R <sub>3</sub>	Unsaturated C <sub>2-5</sub> alkyl

\*a hydrocarbyl group comprises at least C and H, and may optionally comprise one or more suitable substituents.

For the Examiner's ease of reference, and as recited in dependent claim 30, in one particular embodiment, the method of the invention comprises the following process steps:



In arriving at the claimed method, the inventors recognized the problem of consistently providing/obtaining polymerizable monomer compositions in a satisfactory pure form, i.e., having a very low and quantifiable level of impurities, especially cross-linker impurities. Such impurities are often detrimental to the final polymerized product, and can make such polymers unsuitable for use in products such as ocular devices. Moreover, polymers are very difficult to purify. The solution provided by the claimed invention is a process which utilizes a monomeric ketal starting material and an *immobilized acid*. The immobilized acid allows greater control of the reaction kinetics and side reactions, and results in a lower concentration of resulting acidic by-product(s), and following neutralization, of cross-linker. Moreover, the acid can be readily removed to allow facile isolation of the monomer product.

### C. THE CITED ART

U.S. Patent No. 4,056,496 (Mancini). Mancini has been characterized in detail in Applicant's prior Amendment. Portions of those remarks are reiterated here for emphasis.

Most importantly, nowhere does Mancini describe or even remotely suggest the use of an immobilized acid, nor the potential advantages thereof. Further, nowhere does Mancini teach, suggest, or recognize the formation of methacrylic acid as a side-product (let alone a deleterious one) in the reaction described therein, nor the potential problems associated therewith. Nor does Mancini suggest or even remotely recognize the possibility of formation of *any* amount of a cross-linker during a neutralization step.

The solution phase reaction of Mancini is completely different from a process standpoint from that embodied by the Applicant's claims. Moreover, nowhere does Mancini teach or recognize ANY problem associated with the processes described therein - such as acidifying a ketal monomer precursor under highly acidic conditions, which can lead to significant levels of degradation products and therefore resulting impurities, nor the formation of cross-linker in the subject reaction - which can be highly detrimental to the quality of the resulting monomer product, as well as the final polymer product formed via polymerization of the monomer.



Thus, nowhere does Mancini provide the slightest motivation to modify the teachings therein to arrive at the Applicant's claimed invention, since nowhere does Mancini recognize or suggest even the slightest shortcoming with the methods described.

Indeed, rather than suggesting the use of an immobilized acid, Mancini suggests that a preferred method for preparing glyceryl methacrylate is as provided in Example 2, where GMA is prepared via *solution phase* acid hydrolysis of the epoxidized starting material, glycidyl methacrylate. This starting material has a structure that is completely different than the starting material, formula (II), recited in the instant claims.

The main impurity noted in the resulting product mixture is unreacted starting material, which Mancini suggests acts as a *cross-linker* (column 5, lines 23-24). Since the subsequent polymerization method of Mancini involves inclusion of an epoxidized alkyl acrylate (believed to be a cross-linker as stated in column 5, lines 23-35), rather than removal of unreacted starting material (e.g., glycidyl methacrylate), Mancini actually suggests an amount of epoxidized acrylate in the monomer composition ranging from 0% to 30% by weight of the dihydroxy acrylate...most preferably from about 3.2 to about 7.5%. Thus, in no way does Mancini suggest a method that focuses on forming small amounts of cross-linker, in contrast, Mancini actually suggests just the opposite, i.e., that an *increase* in epoxidized acrylate cross-linker may be required (column 5, lines 55-61). Thus, Mancini actually teaches away from one feature of the Applicant's claimed method – i.e., minimizing the amount of cross-linker formed.

In sum, in considering the teachings of Mancini as a whole, in no way does Mancini provide the slightest motivation for using an immobilized acid for any purpose, let alone for reducing side reactions and/or for reducing the amount of acidic and cross-linker reaction side-products.

U.S. Patent No. 5,212,015 (Mitra). Mitra has also been discussed in detail in Applicant's prior Amendment.

Mitra is directed to synthetic routes for providing single isomers of monocarbamate diols, as well as their polymerization. The products of Mitra are stated

to be particularly useful in non-linear optics (NLO). Mitra has absolutely nothing to do with compounds having the structures recited in the instant claims, nor with minimizing formation of either acid or cross-linker reaction by-products during formation of a product having the structure of Applicant's formula (I). Nor is Mitra focused on ophthalmic devices as recited in certain of the instant claims. Rather, Mitra is focused on a problem that is completely unrelated to that addressed by the instant claims – Mitra is directed to the provision of *isomerically pure* monocarbamate diols.

While Mitra is related to providing pure compounds, the focus of Mitra is the provision of *isomerically pure* compounds – not compounds having a greater degree of purity related to low levels of acidic and cross-linker impurities. Thus, the problems addressed by the Applicant's invention and those addressed by Mitra are completely unrelated.

Mitra describes that isomerically pure monocarbamate diols can be prepared by acidification of the corresponding ketals. Mitra further describes that acidification can be carried out using an organic or non-oxidizing inorganic acid, or even using an ion exchange resin. This, however, has nothing to do with the Applicant's claims.

Mitra provides absolutely no motivation or suggestion to modify the compounds that are the very focus of Mitra to arrive at a compound having the structure recited in the Applicant's claims. Nor does Mitra have anything to do with or recognize the problems addressed by the Applicant's invention. Indeed, neither of the references relied upon by the Examiner provides the slightest motivation for the combination made by the Examiner, nor for the modification of the teachings of the subject references to arrive at the claimed invention.

Regarding the Mitra reference, the Examiner is reminded that it is impermissible to use hindsight reasoning based upon the Applicant's disclosure in combining references. In view of the disparate subject matter, i.e., the particular chemical compounds, processes and desired results that are the subject of Mancini and Mitra, it is submitted that the combination of references provided by the Examiner is based, not upon some motivation provided by either of the references themselves, nor by an acknowledgement in either reference of a problem to be solved that is similar in nature to that addressed by the Applicant, but rather, upon the Applicant's disclosure – in an

attempt to arrive at the subject matter of the Applicant's claims – which the references, when combined, clearly fail to do.

U.S. Patent No. 3,845,164 (Goto). Goto is directed to a mixed resin composition and a method of preparing the same. The method involves polymerization of 85% by weight 1,3-butadiene, 5-30% by weight styrene, 3-40% by weight methylmethacrylate, and 0.1-1% by weight of a divinyl compound to form latex particles. The latex particles are then further modified by graft polymerizing thereupon a monomer mixture containing particular weight ranges of methylmethacrylate, styrene, and acrylonitrile, followed by blending the resulting graft copolymer with 95-75 parts by weight of a vinyl chloride polymer. The resulting compositions are stated to be useful for blow-molding, a process employed to make hollow plastic devices. In sum, the patent is directed to (i) overcoming the problem of graft polymer products which develop stress whitening upon the application of force, and (ii) providing blow molded products without the formation of uneven or irregular surfaces.

Goto has absolutely no relevance to the Applicant's claims. The manufacturing process described in Goto, the chemical compositions employed, as well as those ultimately formed, and the problems addressed in Goto have absolutely nothing to do with the Applicant's claims. Goto fails to have any relevance to the Applicant's claims, outside of the fact that the Examiner has cited Goto in the instant rejection.

The Examiner has relied upon Goto at column 4, lines 34-37, for stating the following, *"the pH of the polymerization system ranges from 5-9, especially 6-8. If the pH is outside of the indicated range, hydrolysis of methyl methacrylate occurs to yield methacrylic acid, resulting in an unstable system"*. The polymerization system of Goto is completely unrelated to the method recited in the Applicant's claims. Further, the method currently recited in the Applicant's claims doesn't even involve formation of methyl methacrylate.

In sum, Goto is nothing more but yet another disparate reference that has nothing to do with the method currently recited in the Applicant's claims. Moreover, Goto fails to make up the deficiencies of Martinez and Mitra as characterized above, when considered either singly or in combination therewith.

U.S. Patent No. 6,239,298 (Williamson). Williamson is directed to a fuel lubricity additive. Specifically, Williamson is directed to a synthetic method for preparing a fuel lubricity additive by reacting an unsaturated base oil from vegetable oil sources with a carboxylic acid-diene compound, followed by esterifying or amidifying the carboxylic acid functionality with either a poly-hydroxy or a poly-amine compound to form the final fuel additive. Fig. 1 in Williamson illustrates the structure of an illustrative fuel additive as provided therein.

As in the case of the Goto, Williamson has absolutely no relevance to the instant claims. The chemical synthesis described by Williamson involves completely different classes of chemical compounds, transformation reactions, and ultimate products from those recited in the Applicant's claims. Nothing in this reference is even remotely related to the Applicant's process for forming a polymerizable monomer, nor to the use of an immobilized acid, nor to a reaction in which the amount of cross-linker formed is minimal by virtue of the reaction conditions employed.

This reference fails, as does Goto, to make up for the deficiencies of Mancini and Mitra.

#### **D. ANALYSIS**

As reiterated by the Supreme Court in *KSR International Co. v. Teleflex Inc.*, S. Ct. 1727 (2007); 82 USPQ2d 1385, 1397 (2007), the factors stated in *Graham v. John Deere*, 383, U.S. 1, 148 USPQ 459 (1966) still control an obviousness inquiry. That is to say, the considerations which must be followed in an inquiry directed to the obviousness or non-obviousness of an invention are as follows:

- i. The claimed invention must be considered as a whole (including portions that would lead away from the claimed invention);
- ii. The references must be considered as a whole and must suggest the desirability and thus the obviousness of making the combination (or modification to arrive at the claimed invention); and
- iii. The references must be viewed without the benefit of hindsight afforded by the claimed invention or accompanying specification.

In conducting the above analysis, one must consider the level of ordinary skill in the art at the time of the invention, as well as whether there exists a reasonable expectation of success.

Finally, the prior art reference (or references when combined ) must teach or suggest all claim limitations (MPEP, Section 2142).

The factual inquiries in Graham form the basis for making a determination of obviousness:

- (1) determining the scope and content of the prior art;
  - (2) ascertaining the differences between the claimed invention and the prior art;
- and
- (3) resolving the level of ordinary skill in the pertinent art.

In view of the Examiner's withdrawal of the rejection of the claims in view of Mancini and Mitra, the issue to be considered here is whether the newly cited references, Goto and Williamson, when combined, make up for the deficiencies of Mancini and Mitra. The Applicant respectfully submits that they do not.

The claimed invention and the references relied upon by the Examiner are described in detail in the preceding sections.

In considering the teachings of the primary reference relied upon by the Examiner, Mancini, as a whole, it can be seen that:

- (i) Mancini fails to teach or suggest use of an immobilized acid;
- (ii) Mancini fails to recognize the possibility of formation of an acidic by-product during acidification of a ketal starting material to form a corresponding diol, and more importantly, the problems associated therewith;
- (iii) Mancini fails to recognize the possibility of formation of a cross-linker side-product during neutralization of an acidic product mixture resulting from acidification of a

ketal starting material, and more importantly, the problems associated therewith, and the desirability of reducing the levels of such a cross-linker in the resulting monomer product.

(iv) Mancini even *teaches away* from the essence of the Applicant's claims by pointing to the desirability of a reaction that actually forms significant amounts of cross-linker.

In *KSR (ibid)*, the Court acknowledged the importance of identifying "a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does" in an obviousness determination. (*KSR*, 127 S. Ct. at 1731).

In keeping with the above, it can be seen that Mancini provides absolutely *no motivation* for modifying the teachings therein to arrive at the Applicant's claimed method. That is to say, Mancini provides no motivation for using an immobilized acid – for any reason. Nor do the secondary references, Mitra, Goto, and/or Williamson.

Moreover, the Examiner is reminded that, as a general rule, references that teach away cannot serve to create a prima facie case of obviousness." (*McGinley v. Franklin Sports, Inc.* CAFC 8/21/01 citing *In re Gurley*, 31 USPQ2d 1131, (Fed. Cir. 1994)). In this case, the primary reference relied upon by the Examiner actually teaches away from the present claims by suggesting the desirability of having significant amounts of a cross-linker in the composition, rather than on minimizing cross-linker formation. Therefore, the rejection under 35 U.S.C. §103 over the combination of references cannot be properly maintained.

In an effort to make up for the deficiencies of Mancini, the Examiner has relied upon the teachings of various disparate secondary references: Mitra, Goto and Williamson. While each of these references does describe chemical syntheses (which is about the extent of their relevance to the Applicant's claimed invention), none of these references is even remotely related to the process embodied by the Applicant's claims,

nor the problems addressed by such claims, nor the particular polymerizable monomer formed as a product, as described in detail above. Further, none of these references, when considered either singly or in combination, points to the desirability of using an immobilized acid in a method such as that presently claimed.

Thus, in keeping with *KSR*, and the required Graham analysis, it is submitted that the claims currently pending in the application are non-obvious over Mancini when considered in view of Mitra, Goto, and Williamson.

Withdrawal of the rejection of the claims under 35 U.S.C. §103(a) is therefore respectfully requested.

#### **V. Miscellaneous –Claims 23, 25, and 26**

On page 6 of the Office action, the Examiner has asserted that in view of the types of reactions described in the prior art, e.g., Mancini and Mitra, limitations such as: formation of 0.50 percent of cross-linker, quantitative conversion of the compound of formula (II) to the monomer of formula (I), and formation of 5% or less of a polymer formed by polymerization of the cross linker are inherently possessed therein.

Applicant respectfully rebuts the Examiner's assertion that the art relied upon provides reasonable basis for this assertion, indeed, it provides just the opposite.

In turning to Mancini and examining the experimental results described, it can be seen that Example 1 fails to provide any yield or characterization data for the monomer formed. Example 2 describes reaction of 100 grams of glycidyl methacrylate in the presence of concentrated sulfuric acid, followed by neutralization with base. 18.8 grams (nearly 20%) of unreacted starting material is recovered from the process – this can hardly be said to render inherent the feature of claim 25, which recites essentially *quantitative conversion* of starting material to product. Moreover, Example 2 fails to provide any analytical data at all for the resulting product mixture – thus, there is no basis for the assumption that the feature recited in Applicant's claim 23, i.e., formation of about 0.50 percent or less of cross-linker, is a feature of Example 2, in particular in view of the fact that Mancini fails to even recognize the problems associated with cross-linker

formation. Indeed, the Applicant discusses Mancini and the shortcomings thereof in the specification at page 3, line 25 to page 4, line 3. Finally, the Examples in Mancini describing polymerization with a co-monomer (Examples 3-47) fail to provide any data whatsoever regarding the purity of the resulting polymer product, i.e., the formation of polymer products resulting from polymerization of a cross-linker. Mitra fails to describe reactions of the type embodied in the Applicant's claims, and therefore is irrelevant to the present analysis.

In sum, there is no reasonable basis in the art relied upon by the Examiner for the assertion that the features recited in claims 23, 25, 26 are inherent in the art of record.



## VI. Conclusion

In view of the foregoing, the Applicant submits that all of the claims pending in the application meet the requirements of 35 U.S.C. §112, first and second paragraphs, and patentably define over the cited art. A Notice of Allowance is therefore respectfully requested.

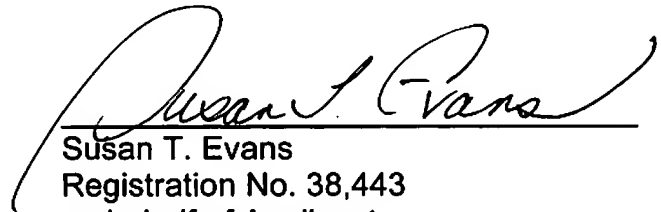
If a telephone conference would expedite the prosecution of the subject application, the Examiner is requested to call the undersigned at (650) 838-4406.

The Commissioner is hereby authorized to charge any deficiency in fees or credit any overpayment to **Deposit Account No. 50-2207**.

Respectfully submitted,

Date:

September 14, 2007

A handwritten signature in cursive script, reading "Susan T. Evans", written over a horizontal line.

Susan T. Evans  
Registration No. 38,443  
on behalf of Applicant

PERKINS COIE LLP  
101 Jefferson Drive  
Menlo Park, CA 94025-1114  
Tel: (650) 838-4406 / Fax: (650) 838-4350